**REMARKS**

The Final Office Action mailed on May 12, 2009, has been received, and carefully considered.

New claim 35 has been added. The claim is directed to a method wherein, in step 1, the serum sample to be tested and the first and second detection substances, or only the second detection substance, are contacted with one same solid support.

The objection to claims 2-12, 14-23, and 25-34 is obviated by appropriate amendment. Specifically, the indefinite article "A" at the beginning of each of these claims has been changed to "The", as suggested by the Examiner.

Claim 3, line 2, has been amended to read "*in that, in step 1(d), it is controlled that . . .*".

In view of the above, the Applicant requests favorable reconsideration of the objections to the claims.

The rejection of claims 1-12 and 14-34 under 35 U.S.C. 112, second paragraph, is obviated by appropriate amendment in part, and traversed in part.

a) Step 1(d) of claim 1 has been amended to recite that control of the presence of human serum in the sample is achieved by detecting whether immunoglobulins of the patient species react with a fourth control antigen containing protein

A of a *Staphylococcus aureus* bacterium. Support for this amendment can be found in original claim 3.

b) In the Applicant's view, the allegation made by the Examiner that there is no correlation step which correlates the *in vitro* serological method for diagnosing microbial agents by immunodetection to the reactions or absence of reaction with the said control antigen, in the event of an IgM assay, is not well founded, and is respectfully traversed.

Indeed, in the event of an IgM assay, the reaction of the first control antigen (non specific IgG) with a said first detection substance (labelled anti-IgM antibody) reflects the presence of rheumatoid factors (anti-IgG IgM).

Similarly, if the second control antigen reacts with the first detection substance, it means that both rheumatoid factor and antinuclear antibody are present within the sample (see specification on pages 11 and 18-19). Accordingly, in the event of an IgM assay, the reaction between the microbial antigen and the serum sample must not take into account whether the first control antigen and second control antigen react with the first detection substance.

Thus, in the event of an IgM assay, if the second detection substance reacts with the first control antigen and the first detection substance reacts with the third control

antigen, it means that there is no rheumatoid factor and no nuclear antibody.

c) Claim 1, step 2, has been objected to because it is alleged that step 2 only detects the presence of the microbial agent, but it does not diagnose microbial agents.

To obviate this objection, the preamble of claim 1 has been amended to recite a method for detecting and quantifying the presence of microbial agents.

d) The term "preferably" in claim 3, line 6, has been deleted. The term "optionally" in claim 1, line 27, has also been deleted.

e) Claim 3 was objected to as being unclear in that it refers to an "attached second detection substance". This is not correct.

The second detection substance is not attached to the solid support, but is included in the tested sample, this later being contacted with the solid support onto which the fourth control antigen is attached.

To more clearly define the invention, claim 3 has been amended to read in part "*by contacting said sample in the presence of said second detection substance with a solid support on which a said fourth control antigen is attached, said second detection substance being an anti-immunoglobulin*

*antibody of the patient species not reacting with said fourth control antigen . . .*"

f) Claims 11 and 20 have been amended to recite proper Markush language.

g) Claim 17 has been amended to recite that the microbial agent to be detected is a class G immunoglobulin.

h) The term "cut-off" has been deleted from claim 21.

In view of the above amendments and remarks, Applicant submits that that the rejection of claims 1-12 and 14-34 under 35 U.S.C. 112, second paragraph, has been overcome. Favorable reconsideration of the rejection is thus urged.

The rejection of claims 1-12 and 13-34 under 35 U.S.C. 102(b) as being anticipated by Wong et al. (U.S. 5,478,753) is again respectfully traversed, for the following reasons.

**a)** Wong et al. specifically relates to an IgM serology assay, while the present invention relates to an assay of both classes M and G or only class G immunoglobulins specific to the microbial agent (see column 1, line 2, as well as the preamble of claims 11-18 of Wong et al.).

Further, Wong et al. relates to calibrator compositions. When an IgM serology assay is concerned, "it is difficult to obtain a sufficient supply of IgM antibodies from individuals to use in calibrator compositions" (see column 1, lines 35-37, of Wong et al.). It is therefore an object of the invention

of Wong et al. to provide an IgM serology assay which utilizes particular calibrator compositions.

More precisely, Wong et al. provides composite antibodies comprising a non-specific IgM linked to a specific non-IgM immunoglobulin, more particularly, a non-specific IgM linked to a specific IgG immunoglobulin.

Wong et al. does not disclose a solid carrier onto which is attached a plurality of control antigens.

More particularly, in Wong et al., the only material disclosed as being immobilized on a solid carrier is a so-called "capture material" which is selected to bind specifically to the composite antibody (see column 2, lines 19-20).

In Wong et al., the only immobilized material is the capture material which is an antibody selected to bind to human non-specific IgG or an antibody selected to bind to the specific non-IgM antibody segment of the composite antibody.

Wong et al. discloses two embodiments:

(i) a first embodiment wherein the capture material immobilized on the solid carrier is selected to bind to the non-specific IgM segment of the composite antibody; and

(ii) a second embodiment wherein the capture material is selected to bind the specific non-IgM antibody, for instance a specific IgG antibody segment of the composite antibody.

Wong et al. does not disclose a solid carrier wherein a non specific IgG is attached on the solid carrier as a first control antigen and a non-specific IgM immunoglobulin is attached to the solid carrier as a third control antigen (in the event of IgM assay).

Moreover, Wong et al. does not disclose nor suggest using a second control antigen made of DNA complex attached to the said solid carrier.

**b)** In Wong et al., the detection substance is selected to bind to both the composite antibody and the specific IgM of the disease agent (see column 2, lines 23-25), while in the method of the present invention the first detection substance comprises an antibody only reacting with any non-specific or specific IgM immunoglobulin of the patient.

**c)** The Applicant believes that there is no basis for the Examiner's assertion that "Wong et al. teaches IgG, IgA, IgD, IgM or IgE as control antigens".

In fact, Wong et al. teaches IgG, IgA, IgD or IgE as specific non-IgM antibody segment of the composite antibody (see column 2, line 2).

The composite antibody of Wong et al. is not equivalent to the non-specific IgG (first control antigen) of the present invention, for the two following reasons:

(i) the composite antibody is not attached to a solid carrier; and

(ii) the composite antibody comprises a specific IgG while the first control antigen of the present invention is a non-specific IgG.

**d)** It is submitted that Wong et al. does not meet the limitations of the claims because the non-specific IgM of the presently claimed invention is attached to a solid support, while nowhere in Wong et al. it is disclosed or suggested that an immobilised material can comprise a non-specific IgM or a non-specific IgG antibody.

e) There is no evidence on record that Wong et al. inherently discloses the inclusion of DNA/histone complex, as alleged by the Examiner. The Applicant respectfully requests that the Examiner indicate a specific reference disclosure in support of such a claim of inherency.

f) Wong et al. fails to disclose or suggest the particular step of the claimed step 2 of the present invention.

For the reasons set forth above, and those set forth in Applicant's response filed on January 15, 2009, the Applicant submits that the Wong et al. reference does not teach or suggest each and every element of the presently claimed

invention. Favorable reconsideration of the rejection under 35 U.S.C. 102(b) is therefore urged.

It is believed that the present application is now in condition for allowance, and an early allowance to this effect is respectfully urged. If any final points remain that can be clarified by telephone, Examiner Hines is encouraged to contact Applicant's attorney at the number indicated below.

Respectfully submitted

Malcolm J. MacDonald

Date: August 12, 2009

Malcolm J. MacDonald
Reg. No. 40,250
(703) 837-9600 Ext. 24